IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT : Moscarello et al

INVENTION: : METHOD FOR DIAGNOSING MULTIPLE

SCHLEROSIS AND AN ASSAY THEREFOR

SERIAL NUMBER : 09/992,174

FILING DATE : November 14, 2001

EXAMINER: : Counts, Gary W.

GROUP ART UNIT : 1641

ATTORNEY DOCKET NO. : 2132.024

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to the Duty to Disclose under 37 C.F.R. §1.56, the references cited on the accompanying form PTO-1449 are hereby brought to the attention of the Examiner for independent evaluation. A copy of each reference is enclosed.

In accordance with 37 C.F.R. §1.97(e), Applicants hereby certify that each item of information contained in the accompanying Supplemental Information Disclosure Statement filed concurrently herewith was cited in a communication from a foreign patent office, namely an International Search Report for a counterpart International patent application. A copy of the International Search Report is also enclosed, which satisfies the requirement for a concise statement of relevancy pursuant to M.P.E.P. §609 (1995).

Because this Supplemental Information Disclosure Statement is submitted more than three months from issuance of the International Search Report and after receipt of a substantive Office Action on the merits, the Commissioner for Patents is hereby authorized to charge the appropriate fee of \$180.00 required under 37 CFR §1.17(p) to Deposit Account No. 50-1803.

Applicants submit that the present invention is patentable over these references.

Accordingly, pursuant to 37 C.F.R. §1.97(e), Applicants request consideration and entry of the Supplemental Information Disclosure Statement.

Date: 5/31/2005

Respectfully submitted,

Ferris H. Lander

Registration No. 43,377

McHale & Slavin, P.A.

2855 PGA Boulevard

Palm Beach Gardens, FL 33410

Telephone: (561) 625-6575 Facsimile: (561) 625-6572

\\Ns2\server\CLIENT FILES\2100-2199\2132 -Syn-X\2132_000024 - MS Diagnostic\References\Applicant's IDS References\2132.024suppids1.wpd

PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the paper of the Paperwork Reduction Act of 1995, no persons the 1995, no

JUN 0 1 2005

Substitute for form 1449/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| Complete if Known | | | | |
|------------------------|------------------|--|--|--|
| Application Number | 09/992,174 | | | |
| Filing Date | 11/14/2001 | | | |
| First Named Inventor | Mario Moscarello | | | |
| Art Unit | 1641 | | | |
| Examiner Name | Gary W. Counts | | | |
| Attorney Docket Number | 2132.024 | | | |

| U. S. PATENT DOCUMENTS Examiner Cite Document Number Publication Date Name of Patentee or Pages, Columns, Lines, WI | | | | | | |
|--|--------------|---|--------------------------------|-----------------------------|---|--|
| Examiner Initials* | Cite No.1 | Document Number | Publication Date MM-DD-YYYY | Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevan | |
| | <u></u> | Number-Kind Code ^{2 (# known)} | | | Figures Appear | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| <u> </u> | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |
| | | US- | | | | |

| | | IGN PATENT DOCL | | | _ |
|---------------|--|--|--|--|---|
| Examiner Cite | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages | |
| | Country Code ^{3 -} Number ^{4 -} Kind Code ⁵ (<i>if known</i>) | MM-DD-YYYY | | Or Relevant Figures Appear | T |
| | EP 0 519 536 | 12/23/1992 | Pro-Soma Sarl | | |
| | | | | | |
| | | | | | L |
| | | | | | ┡ |
| | | | | | L |
| | No.1 | No. ¹ Country Code ³ Number ⁴ Kind Code ⁵ (if known) | No.¹ Date MM-DD-YYYY Country Code³-Number⁴-'Kind Code⁵ (if known) | No. ¹ Date MM-DD-YYYY Country Code ³ Number ⁴ Kind Code ⁵ (if known) Date MM-DD-YYYY | No.1 Date MM-DD-YYYY Applicant of Cited Document Where Relevant Passages Or Relevant Figures Appear |

| Examiner | Date | |
|-----------|------------|--|
| Signature | Considered | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

JUN 01 2005

PTO/SB/08B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| Substitute for form 1449/PTO | | | - | Complete if Known | | |
|-----------------------------------|-----------------------------|---------------|----------------|------------------------|------------------|--|
| Substitute | Substitute to form 1449/FTO | | | Application Number | 09/992,174 | |
| INFO | RMATIO | N DIS | CLOSURE | Filing Date | 11/14/2001 | |
| STATEMENT BY APPLICANT | | | PPLICANT | First Named Inventor | Mario Moscarello | |
| | | | | Art Unit | 1641 | |
| (Use as many sheets as necessary) | | Examiner Name | Gary W. Counts | | | |
| Sheet | 2 | of | 2 | Attorney Docket Number | 2132.024 | |

| Examiner | Cite | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of | |
|-----------|------------------|---|----------------|
| Initials* | No. ¹ | the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | | J. TERRYBERRY et al, "Autoantibodies in Neurodegenerative Diseases: Antigen-Specific Frequencies and Intrathecal Analysis", Neurobiology of Aging, 19(3):205-216 (1998) | |
| | | M. GUPTA, "Myelin Basic Protein and Demyelinating Diseases", Critical Review in Clinical Laboratory Sciences, 24(4):287-314 (1987) | |
| | | L. HUGHES et al, "Antibody Responses to Acinetobacter spp. and Pseudomonas aeruginosa in Multiple Sclerosis: Prospects for Diagnosis Using the Myelin-Acinetobacter-Neurofilament Antibody Index", Clinical and Diagnostic | |
| | | Laboratory Immunology, 8(6):1181-1188 (November, 2001) | |
| | | K. AKIYAMA, "Highly SensitiveD-Galactosidase-Linked Immunosorbent Assay for Anti-Myelin Basic Protein Antibody", Japan J. Exp. Med., 53(4):181-185 (August, 1983) | |
| | | S. MAZZUCCO et al, "A Synthetic Glycopeptide of Human Myelin Oligodendrocyte Glycoprotein to Detect Antibody Responses in Multiple Sclerosis and Other Neurological Diseases", Bioorganic & Medicinal Chemistry Letters, 9(2):167-172 (January, 1999) | |
| | | A. CHAMCZUK et al, "A Rapid ELISA-based Serum Assay for Myelin Basic Protein in Multiple Sclerosis", J. Immunol. Meth., 262(1-2):21-27 (April, 2002) | |
| | | | |
| | | | |
| | | | |

| Examiner | Date | |
|-----------|------------|--|
| Signature | Considered | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.